# **Complete Summary**

## **GUIDELINE TITLE**

Local regional recurrence (LR) and salvage surgery--breast cancer.

# BIBLIOGRAPHIC SOURCE(S)

Green S, Shank BM, Haffty BG, Halberg FE, Mitchell SE, Rabinovitch RA, Solin LJ, Strom EA, Taylor ME, White JR, Cobleigh MA, Edge SB, Mauch PM, Expert Panel on Radiation Oncology-Breast Work Group. Local regional recurrence (LR) and salvage surgery -- breast cancer. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 12 p. [41 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: McCormick B, Mendenhall NP, Shank BM, Haffty BG, Halberg FE, Martinez AA, McNeese MD, Mitchell SE, Rabinovitch RA, Solin LJ, Taylor ME, Singletary SE, Leibel S. Local regional recurrence and salvage surgery. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215 (Suppl): 1181-92.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## SCOPE

# DISEASE/CONDITION(S)

Breast cancer

- Local-regional recurrence after breast-conserving therapy (BCT)
- Local-regional recurrence after modified radical mastectomy (MRM)

## **GUIDELINE CATEGORY**

Risk Assessment Treatment

## CLINICAL SPECIALTY

Internal Medicine Oncology Radiation Oncology Radiology Surgery

#### INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

## GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic treatment procedures for patients with local-regional recurrence of breast cancer after breast-conserving therapy (BCT) or modified radical mastectomy (MRM)

## TARGET POPULATION

Women with local-regional recurrence of breast cancer after breast-conserving therapy (BCT) or modified radical mastectomy (MRM)

## INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Chemotherapy
- 2. Simple mastectomy (SM)
  - Alone
  - Plus sentinel lymph node biopsy (SNLB)
  - Plus lymph node dissection (LND) or modified radical mastectomy
- 3. Lumpectomy
  - Alone
  - Plus radiation therapy (RT)
  - Plus lymph node (LN) staging and RT
- 4. Quadrantectomy
- 5. Hormone therapy
- 6. Complete excision of recurrence
- 7. Hyperthermia
  - Alone

- Plus RT
- 8. RT, including consideration of volumes, doses, and modality (wedge filters, computer planning, photons with bolus, electrons)
- 9. Modified radical mastectomy

#### MAJOR OUTCOMES CONSIDERED

- Ten-year overall and disease-free survival rates
- Recurrence rates

## METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals and the major applicable articles were identified and collected.

#### NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

# DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

# COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

## RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

# ACR Appropriateness Criteria®

<u>Clinical Condition</u>: Local Regional Recurrence (LR) and Salvage Surgery—Breast Cancer

<u>Variant 1</u>: 37-year-old, 1.2 cm LR in breast 2.5 years after BCT with lumpectomy and axillary node dissection + RT for T1bN0 lesion. ER/PR (-). EOD workup negative.

Treatment	Appropriateness Rating	Comments	
	Principles of Treatment		
Chemotherapy	8	Consider clinical trial.	
Simple mastectomy (SM)	8		
SM + sentinel lymph node biopsy (SLNB)	3		
SM + lymph node dissection (LND) or modified radical mastectomy	2		
Lumpectomy	2	Only in a clinical trial	
Quadrantectomy	2		
Lumpectomy + RT	1	Only in a clinical trial	
Hormone therapy	1		
	RT Volu	ımes	
Whole breast +/- boost	1		
Chest wall (after mastectomy)	1		
Supraclavicular (adequate LND)	1		
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate			

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2</u>: 52-year-old, 0.5 cm LR in breast 15 years after BCT with lumpectomy and axillary node dissection + RT for T1bNO lesion. ER/PR (+). EOD workup negative.

Treatment	Appropriateness Rating	Comments
	Principles of	Treatment
Simple mastectomy (SM)	8	
SM + SLNB	3	
SM + LND or modified radical mastectomy	2	
Lumpectomy	3	Only in a clinical trial
Quadrantectomy	3	
Lumpectomy + RT	1	Only in a clinical trial
RT Volumes		
Whole breast +/- boost	1	
Chest wall (after mastectomy)	1	
Supraclavicular (adequate LND)	1	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

 $\underline{\text{Variant 3}}$ : 60-year-old, simultaneous breast skin + SCL recurrence 3 years after BCT with lumpectomy + RT for T1bN0 lesion. ER/PR (-). EOD workup negative.

Treatment	Appropriateness Rating	Comments
Principles of Treatment		
Chemotherapy	9	
Simple mastectomy	2	

Treatment	Appropriateness Rating	Comments	
(SM)			
SM + LND or modified radical mastectomy	2		
Lumpectomy	2		
Quadrantectomy	2		
Lumpectomy + RT	2		
Hormone therapy	2		
RT Volumes			
Supraclavicular (adequate LND)	8		
Whole breast +/- boost	2		
Chest wall (after mastectomy)	2		
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate			

<u>Variant 4</u>: 42-year-old, 3.0 cm LR in breast 6 years after BCT + chemo for T1cN0 lesion. ER/PR (-). EOD workup positive: liver and multiple bone metastases.

Treatment	Appropriateness Rating	Comments
	Principles of	Treatment
Chemotherapy	9	
Simple mastectomy (SM)	2	
SM + LND or modified radical mastectomy	2	
Lumpectomy	2	
Quadrantectomy	2	

Treatment	Appropriateness Rating	Comments	
Lumpectomy + RT	2		
Hormone therapy	2		
	RT Volumes		
Whole breast +/- boost	2		
Chest wall (after mastectomy)	2		
Supraclavicular (adequate LND)	2		
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate			

<u>Variant 5</u>: 55-year-old, 1.5 cm LR in breast 7 years after BCT with lumpectomy only + RT for original diagnosis of DCIS, not otherwise specified. Biopsy: invasive ductal carcinoma. ER/PR (-). EOD workup negative.

Treatment	Appropriateness Rating	Comments
	Principles of	Treatment
Chemotherapy	8	
SM + LND or modified radical mastectomy	8	
SM + sentinel lymph node biopsy (SLNB)	8	
Simple mastectomy	2	
Lumpectomy	2	
Quadrantectomy	2	
Lumpectomy + RT	2	
Hormone therapy	2	
RT Volumes		

Treatment	Appropriateness Rating	Comments
Whole breast +/- boost	2	
Chest wall (after mastectomy)	2	
Supraclavicular (adequate LND)	2	

Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 6</u>: 55-year-old, 7 nodules (1-2 cm diameter) along MRM scar 3 years after MRM+ chemo + adjuvant chest wall/SCL RT (50 Gy). Primary and LR both ER/PR (-).

Treatment	Appropriateness Rating	Comments
Complete excision of recurrence	8	If technically possible with primary closure with or without simple advancement flap
Chemotherapy	7	Consider for study.
Radiation therapy	7	Use judgment on RT volume.
Hyperthermia + RT	6	
Hormone therapy	1	
Hyperthermia alone	1	

Appropriateness Criteria Scale
1 2 3 4 5 6 7 8 9
1 = Least appropriate 9 = Most appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 7</u>: 60-year-old, 2 cm nodule on MRM scar 4 years after MRM + chemo for T1N1 [3 LNs (+)]. FNA (+). Primary ER/PR (+): PR (+): Nodule ER/PR (+) by immunohistology. Asymptomatic EOD workup negative.

Treatment	Appropriateness Rating	Comments	
	Principles of Treatment		
Complete excision of recurrence	8		
Radiation therapy	8		
Hormone therapy	8		
Chemotherapy	5		
Hyperthermia	2		
	RT Volu	ımes	
Chest wall	9		
Supraclavicular fossa	8		
Axilla	2		
Internal mammary nodes (IMN)	2		
	RT Do	ses	
Chest Wall: 4000 cGy/16-20 fractions	2		
Chest Wall: 4500- 4680 cGy/23-26 fractions	2		
Chest Wall: 5000- 5040 cGy/25-28 fractions	8		
Supraclavicular: 4000 cGy/16-20 fractions	2		
Supraclavicular: 4500- 4680 cGy/23-26 fractions	8		
Supraclavicular: 5000- 5040 cGy/25-28 fractions	8		
IMN (excluding gross disease): 4500-4680 cGy/23-26 fractions	2		
IMN (excluding gross	2		

Treatment	Appropriateness Rating	Comments
disease): 5000-5040 cGy/25-28 fractions		
Total dose including boost: 5000 cGy	2	
Total dose including boost: 5100-5900 cGy	8	
Total dose including boost: 6000-7000 cGy	8	
Total dose including boost: >7000 cGy	2	
Modality/Other Factors		
Wedge filters (chest wall photons)	8	
Computer planning	8	
Photons with bolus (chest wall)	8	
Electrons	8	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 8</u>: 42-year-old, 2 cm parasternal lump (2nd interspace) + 1 cm medial SCL Node 9 months after MRM + chemo for T2N1 [4 LNs (+)]. Primary ER/PR (+): PR (+). Lump ER/PR (+) by immunohistology. EOD workup negative.

Treatment	Appropriateness Rating	Comments
	Principles of	Treatment
Chemotherapy	9	
Radiation therapy	9	
Hormone therapy	8	
Complete excision of	2	

Treatment	Appropriateness Rating	Comments
recurrence		
Hyperthermia	2	
	RT Volu	ımes
Chest wall	9	
Supraclavicular fossa	9	
Internal mammary nodes (IMN)	9	
Axilla	3	
	RT Do	ses
Chest Wall: 4000 cGy/16-20 fractions	2	
Chest Wall: 4500- 4680 cGy/23-26 fractions	2	
Chest Wall: 5000- 5040 cGy/25-28 fractions	8	
Supraclavicular: 4000 cGy/16-20 fractions	2	
Supraclavicular: 4500- 4680 cGy/23-26 fractions	2	
Supraclavicular: 5000- 5040 cGy/25-28 fractions	8	
IMN (excluding gross disease): 4500-4680 cGy/23-26 fractions	5	
IMN (excluding gross disease): 5000-5040 cGy/25-28 fractions	8	
Total dose including gross disease site boost: 5000 cGy	2	
Total dose including	3	

Treatment	Appropriateness Rating	Comments
gross disease site boost: 5100-5900 cGy		
Total dose including gross disease site boost: 6000-7000 cGy	8	
Total dose including gross disease site boost: >7000 cGy	3	
Modality/Other Factors		
Wedge filters (chest wall photons)	8	
Computer planning	8	
Photons with bolus (chest wall)	8	
Electrons	8	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 9</u>: 42-year-old, 2.0 cm nodule on MRM scar 6 years after MRM for T1bN0 lesion. FNA (+). ER/PR (+) nodule. Asymptomatic EOD workup negative.

Treatment	Appropriateness Rating	Comments
Principles of Treatment		
Complete excision of recurrence	8	
Radiation therapy	8	
Chemotherapy	8	
Hormone therapy	8	
Hyperthermia	2	
RT Volumes		

Treatment	Appropriateness Rating	Comments
Chest wall	9	
Supraclavicular fossa	8	
Internal mammary nodes (IMN)	5	
Axilla	2	
	RT Do	ses
Chest Wall: 4000 cGy/16-20 fractions	2	
Chest Wall: 4500- 4680 cGy/23-26 fractions	2	
Chest Wall: 5000- 5040 cGy/25-28 fractions	8	
Supraclavicular: 4000 cGy/16-20 fractions	2	
Supraclavicular: 4500- 4680 cGy/23-26 fractions	8	
Supraclavicular: 5000- 5040 cGy/25-28 fractions	8	
IMN (excluding gross disease): 4500-4680 cGy/23-26 fractions	8	
IMN (if treated): 5000-5040 cGy/25-28 fractions	8	
Total dose including gross disease site boost: 5000 cGy	2	
Total dose including gross disease site boost: 5100-5900 cGy	3	
Total dose including gross disease site boost: 6000-7000 cGy	8	

Treatment	Appropriateness Rating	Comments
Total dose including gross disease site boost: >7000 cGy	2	
Modality/Other Factors		
Wedge filters (chest wall photons)	8	
Computer planning	8	
Photons with bolus (chest wall)	8	
Electrons	8	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

<u>Variant 10</u>: 55-year-old, 1.5 cm LR in breast 7 years after BCT with lumpectomy only for 1.2 cm tubular CA. Biopsy: tubular CA. ER/PR (-). EOD workup negative.

Treatment	Appropriateness Rating	Comments	
	Principles of Treatment		
Simple mastectomy (SM) + lymph node dissection (LND)	8		
Modified radical mastectomy	8		
Lumpectomy + RT	8		
Lumpectomy + LN staging + RT	8		
Simple mastectomy (SM)	2		
Lumpectomy	2		
Quadrantectomy	2		

Treatment	Appropriateness Rating	Comments
RT Volumes		
Whole breast +/- boost	8	
Chest wall (after mastectomy)	2	
Supraclavicular (adequate LND)	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

For almost two decades, the major focus of radiation oncologists specializing in the management of breast cancer has been on performing both randomized and nonrandomized trials comparing breast-conserving surgery and radiation with the more traditional modified radical mastectomy. With the gradual acceptance of these two local regional therapies as equivalent in the management of early-stage invasive breast cancer by the late 1980s, attention was then refocused on identifying factors (pathologic, patient, or therapy-oriented), that predicted for the success or failure of the treatment locally.

Accompanying these very real clinical goals was a philosophical discussion on the relationship of a local recurrence to the development of distant failure and eventually death from the disease. Early on, it was noted that the survival rate from salvage surgery for failures in the conserved breast was 50% or higher at five years, and local failures following breast-conserving surgery and radiation were somehow classified as "different" from local regional failures following mastectomy, which were readily linked with the development of distant disease and thought incurable.

The success story of systemic chemotherapy and hormone therapy in the management of breast cancer needs to be emphasized as well. The survival and disease-free survival patterns of patients have changed. Women who decades ago would have died rapidly from distant disease may now survive long enough to exhibit a local regional failure. Thus, our thoughts on the consequences of these failures without distant disease must change as well. A prospective randomized trial from the European Organization for Research and Treatment of Cancer (EORTC) group comparing mastectomy with breast-conserving surgery and radiation in patients of similar stages with similar systemic therapy surprisingly showed almost identical 5-year survival rates following salvage procedures for local-only failures in both the breast-conserved arm and the mastectomy arm.

The relationship between local failure and distant failure must be reanalyzed in both groups of patients (i.e., those treated with mastectomy and those treated with breast-conserving surgery and radiation). Conversely, the importance of obtaining local control with initial treatment must remain important not only for the goal of preventing either the loss of the breast in the conserved patients or painful and difficult-to-control local failure in the mastectomy patients, but also to potentially decrease subsequent distant metastases that may be associated with these local failures. As chemotherapeutic regimens for the risk of distant disease become more effective, this goal of ensuring local control takes on a potentially greater importance. Although some researchers have hypothesized that local failure in the conserved breast is a predictor of distant failure as well, others have challenged this concept and concluded that a recurrence in the breast causes distant metastases. Data from the Early Breast Cancer Trialists Collaborative Group (EBCTCG) demonstrate that treatments resulting in improved local control may lead to decrease in breast cancer mortality. The overview analysis also suggests that avoidance of local recurrence in a conserved breast (after breastconserving surgery and radiation) and avoidance of a local recurrence elsewhere (i.e., the chest wall or regional nodes) after mastectomy are of comparable relevance to 15-year breast cancer mortality.

## Recurrence after Breast-Conserving Surgery and Radiation

Predictors for local regional failure after both breast-conserving surgery and radiation can be divided into three broad categories. The first involves factors related to the patient herself. Very young age at the time of diagnosis, defined as either younger than age 30 or 40, appears to be a strong predictor.

The second category consists of tumor factors that have been analyzed after breast-conserving surgery. Most studies have found that positive microscopic margins, gross multifocality, and an extensive intraductal component (EIC) are associated with a higher risk of recurrence in the conserved breast. Some series have noted larger size and lymphatic vessel invasion as risk factors.

The third category consists of therapeutic factors, the most important of which is the omission of breast radiation, for predicting local recurrence. Numerous studies have demonstrated that radiation therapy dramatically reduces the risk of recurrence in the breast. Patients receiving systemic chemotherapy or hormone therapy appear to have higher local control rates, all else being equal, than those who do not. The size of the surgical procedure affects local control in many series, which can also be related to the margin status. The addition of a radiation boost to the lumpectomy cavity may decrease the incidence of a recurrence in the conserved breast, particularly in women (younger than age 40).

The generally recommended treatment for locally recurrent breast cancer after breast conservation is salvage mastectomy. This results in local control in 85%-95% of patients with an ipsilateral breast tumor recurrence (IBTR). Following an IBTR, overall survival rates range from 45%-80% at 5 years and 40%-65% at 10 years.

In patients who are operable after local recurrence only, involvement of the skin or multiple positive lymph nodes appears to be associated with a larger risk of subsequent failure than recurrence in breast tissue only. The incidence of nodal

recurrence in breast-conserving series is low and has not been a major management problem. However, involvement of the nodes would have significant impact on outcome; therefore, assessment of the axillary status for an invasive local recurrence of the breast should be considered. The role of SLNB in this scenario remains to be defined. Preliminary data indicate that SLNB may be performed at the time of salvage surgery, as previous breast or axillary surgery may not be a contraindication to SLNB.

Because of the relationship between local recurrence and distant failure, systemic therapy must also be considered in the treatment program of this patient group. To date, no published series has shown a statistically significant improvement in subsequent outcome with the administration of salvage chemotherapy or hormonal intervention at the time of local recurrence. Factors to be considered in this clinical decision include prior systemic therapy, if any; extent of recurrence; time interval from initial treatment to recurrence; tumor hormone receptor status, patient age, and general medical condition. The National Surgical Adjuvant Breast and Bowel Project (NSABP) are evaluating the benefit of adjuvant chemotherapy following radical resection of locoregionally recurrent breast cancer. This prospective randomized trial is currently open to accrual.

Some patients who present with an IBTR following conservative surgery and radiation therapy may have a new primary tumor as opposed to a true local recurrence. The second breast tumor has been defined as a new primary if it is distinctly different from the original tumor with respect to histology subtype, if it presents in a different location in the breast, or if flow cytometry has changed from aneuploid to diploid. The time interval between the original primary and the second tumor is generally considerably greater for new primaries compared to true recurrences (7.3 vs. 3.7 years). Ten-year overall survival rates (75% vs. 55%) and distant disease-free survival rates (85% vs. 41%) tend to be much better for patients with new primaries compared to those with true recurrences. Thus the diagnosis of a new primary as opposed to a true recurrence implies a different natural history and prognosis, and has different implications for therapeutic management. Unfortunately, most series addressing breast tumor recurrences do not adequately distinguish between the two entities. This may be of particular importance to breast cancer management in young women with BRCA 1/2 mutations, who are at increased risk for breast tumor recurrences due to new primaries.

Patients with DCIS who undergo breast-conserving therapy and subsequently sustain a recurrence in the treated breast appear to have an excellent outcome following salvage therapy. In most series, about half of the recurrences are invasive, with the other half recurring as DCIS. Nevertheless, almost all these patients can be cured by mastectomy. One study reported an overall survival rate of 92% and a distant metastasis-free survival rate of 89% at 8 years, following salvage therapy.

## Recurrence after Mastectomy

Risk factors for local regional failure following mastectomy can also be divided into clinical, pathological, and treatment-related categories. Young age (defined as younger than 35 or 40 years) has been associated with an increased risk of locoregional recurrence after mastectomy. Patients with certain pathological risk

factors, principally four or more involved nodes, T3 or T4 tumors, lymphatic vessel invasion, or involvement of the overlying skin or underlying muscle, are at increased risk for local regional recurrence. Patients whose mastectomy specimens yield a positive deep margin are also at increased risk for such failure. Elective postmastectomy irradiation reduces this risk. There is controversy regarding the risk of chest wall recurrence in the subgroup of patients with one to three positive nodes and their need for postmastectomy radiation therapy (See the Appropriateness Criteria® topic on Post-mastectomy Radiation Therapy).

Systemic therapy appears to have an impact on locoregional control. In the most recent meta-analysis of systemic therapy from the EBCTG, five years of tamoxifen reduced the local recurrence rate by about one-half in women with hormone receptor-positive disease (local recurrence ratio of 0.47), while, irrespective of hormone receptor status, polychemotherapy reduced it by about one-third (ratios 0.63-0.70 depending on patient age).

In contrast to local recurrence in the breast following BCT, local chest wall or regional recurrence of breast cancer, or both, following mastectomy carries a worse prognosis. Five year survival rates range from 35%-75% and 10 year survival rates range from 25%-55%. Long-term control of the local regional disease is achieved in only 45%-70% of patients. Most patients develop distant metastases. Prognostic factors include the extent of disease initially and at recurrence, the disease-free interval, and the ER status as well as the use of surgical excision, radiation, and hormonal therapy. Aggressive attempts at controlling the local-regional recurrence are warranted, however, because patients with uncontrolled local-regional disease are usually symptomatic, are more likely to develop distant metastases, and die sooner than patients whose local-regional recurrences are controlled.

A multidisciplinary approach is required for the management of a chest wall recurrence after mastectomy. Surgical resection should be performed if the size and location of the recurrence permit. In patients who have not received prior radiation therapy, local-regional recurrences are managed with high-dose irradiation. Local-regional recurrence after mastectomy is a harbinger of distant metastases, so systemic treatment should also be considered. If the patient is ER positive, tamoxifen, an aromatase inhibitor (depending on menopausal status) or ovarian ablation may be used. If the patient is ER negative, then chemotherapy may be given.

Treatment Guidelines after Breast Conserving Therapy

For patients failing BCT that included standard whole-breast radiation and an axillary node dissection, simple mastectomy is recommended as the local treatment of choice when the failure is confined to the breast parenchyma and is operable.

In the clinical situation involving recurrence in the treated breast, along with a supraclavicular nodal failure, the recommendation is for radiation to the untreated supraclavicular area, and chemotherapy. Although this pattern of recurrence is not common, it is viewed as systemic failure based on existing evidence. Similarly, for patients with clear distant metastases as well as local failure, primary systemic management is recommended rather than mastectomy.

In the rare clinical situation of a local recurrence for a patient whose initial treatment consisted only of a wide local excision without radiation or axillary dissection, treatment options include either modified radical mastectomy or lumpectomy, axillary nodal evaluation, and radiation therapy, in other words, the decision tree open to a patient with newly diagnosed breast cancer, provided the systemic work-up was negative.

Given the situation of a patient who had had lumpectomy plus radiation therapy only, for a diagnosis of DCIS initially, with recurrence of operable invasive cancer, modified radical mastectomy is recommended, as well as consideration of systemic therapy.

#### **Abbreviations**

- BCT, breast-conserving therapy
- CA, carcinoma
- DCIS, ductal carcinoma in situ
- EOD, extent of disease
- ER, estrogen receptor
- FNA, fine-needle aspiration
- LN, lymph node
- LND, lymph node dissection
- MRM, modified radical mastectomy
- RT, radiation therapy
- PR, progesterone receptor
- SCL, supraclavicular
- SLNB, sentinel lymph node biopsy

## CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

Selection of appropriate radiologic procedures for management of patients with loco-regional recurrence of breast cancer

#### POTENTIAL HARMS

Not stated

## QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to quide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

**IMPLEMENTATION TOOLS** 

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

LOM DOMALN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

Green S, Shank BM, Haffty BG, Halberg FE, Mitchell SE, Rabinovitch RA, Solin LJ, Strom EA, Taylor ME, White JR, Cobleigh MA, Edge SB, Mauch PM, Expert Panel on Radiation Oncology-Breast Work Group. Local regional recurrence (LR) and salvage surgery -- breast cancer. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 12 p. [41 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## DATE RELEASED

1996 (revised 2006)

## GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

# SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

## **GUIDELINE COMMITTEE**

Committee on Appropriateness Criteria, Expert Panel on Radiation Oncology— Breast Work Group

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Sheryl Green, MB, ChB; Brenda M. Shank, MD, PhD; Bruce G. Haffty, MD; Francine E. Halberg, MD; Sandra E. Mitchell, MD; Rachel Abrams Rabinovitch, MD; Lawrence J. Solin, MD; Eric A. Strom, MD; Marie E. Taylor, MD; Julia R. White, MD; Melody A. Cobleigh, MD; Stephen B. Edge, MD; Peter M. Mauch, MD

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: McCormick B, Mendenhall NP, Shank BM, Haffty BG, Halberg FE, Martinez AA, McNeese MD, Mitchell SE, Rabinovitch RA, Solin LJ, Taylor ME, Singletary SE, Leibel S. Local regional recurrence and salvage surgery. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215 (Suppl): 1181-92.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® Anytime, Anywhere $^{\text{TM}}$  (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

# AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>American College of Radiology (ACR) Web</u> site.

#### PATIENT RESOURCES

None available

## **NGC STATUS**

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Date Modified: 9/25/2006